

I claim:

1. A micro or nano-particulate drug composition comprising:

a drug substance; and

5 a surfactant;

wherein said surfactant and said drug substance form a surfactant-drug substance matrix at a temperature above said matrix's melting temperature and wherein said surfactant is miscible with said drug substance and does not chemically bond with said drug substance;

and wherein said drug substance and said surfactant form a non-crystalline substance or micro or nano-sized crystals containing said drug while being cooled to room temperature under a shearing force.

2. The drug of claim 1, wherein said surfactant-drug substance matrix has a melting point less than the decomposition temperature of said drug substance.

3. The drug of claim 1, wherein said crystals have a particle size of less than 5 microns.

4. The drug of claim 1, wherein said crystals have a particle size of less than 400 nm.

5. The drug of claim 1, wherein said crystals have a particle size of less than 250 nm.

6. The drug of claim 1, wherein an average particle size of said crystals is less than about 100 nm.

7. The drug of claim 1, wherein an average particle size

of said crystals is less than about 250 nm.

8. The drug of claim 1, wherein at least 50% of said crystals have a particle size less than 5 microns.

9. The drug of claim 1, wherein at least 75% of said  
5 crystals have a particle size less than 5 microns.

10. The drug of claim 1, wherein said surfactant has a melting point at about room temperature.

11. The drug of claim 1, wherein said drug substance is selected from the group consisting of: analgesics, anti-  
10 inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents,  
15 immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging  
20 agents, diuretics, dopaminergics, haemostatics, immuriological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents,  
25 stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, xanthines, and mixtures thereof.

12. The drug of claim 1, wherein said surfactant is an organic excipient.

13. The drug of claim 12, wherein said excipient is selected from the group consisting of low molecular weight oligomers, natural products, gelatin, casein, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, macrogol ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidol silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethycellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, and polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone, dextran, lecithin, polyvinylpyrrolidone, and organic solvent.

14. The drug of claim 1, wherein said surfactant is nonionic or anionic.

15. The drug of claim 1, wherein said drug is used in a pharmaceutically acceptable carrier.

16. The drug of claim 15, wherein said pharmaceutically

acceptable carrier is selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, buffers, and absorbents.

17. The drug of claim 16, wherein said binder is selected from the group consisting of hydroxypropyl-methylcellulose, ethylcellulose, povidone, acrylic, methacrylic acid co-polymers, pharmaceutical glaze, gums, and milk derivatives.

~~16~~. A method of making a micro and nano-particulate drug, the steps comprising:

providing a drug substance-surfactant mixture;

melting the mixture at a temperature above said mixture's melting temperature; and

cooling the mixture under high shear to approximately room temperature, wherein a non-crystalline substance forms or crystals precipitate coated with said surfactant during crystallization.

19. The method of claim 18, wherein said mixture is melted below the decomposition temperature of said drug substance.

20. The method of claim 18, wherein said non-crystalline substance is flowable.

21. The method of claim 20, wherein said drug substance is micronized prior to adding to said surfactant.

22. The method of claim 18, wherein said drug substance is selected from the group consisting of: analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immuriological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, xanthines, and mixtures thereof.
23. The method of claim 18, wherein said surfactant is an organic excipient.
24. The method of claim 23, wherein said excipient is selected from the group consisting of low molecular weight oligomers, natural products, gelatin, casein, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glyceryl

- monostearate, cetostearl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, macrogol ethers, polyoxyethylene castor oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, polyoxyethylene stearates, colloidol silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethycellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, and polyvinylpyrrolidone, polyvinyl alcohol, polyvinyl pyrrolidone, dextran, lecithin, polyvinylpyrrolidone, and organic solvent.
25. The method of claim 18, wherein said surfactant is nonionic or anionic.
26. The method of claim 18, wherein said drug is used in a pharmaceutically acceptable carrier.
27. The method of claim 26, wherein said pharmaceutically acceptable carrier is selected from the group consisting of diluents, binders, adhesives, lubricants, plasticizers, disintegrants, colorants, bulking substances, flavorings, sweeteners, buffers, and absorbents.
28. The method of claim 27, wherein said binder is selected from the group consisting of

hydroxypropylmethylcellulose, ethylcellulose, povidone,  
acrylic, methacrylic acid co-polymers, pharmaceutical  
glaze, gums, and milk derivatives.

5

10

15

20

25

100227-66222001